

## REMARKS

Claims 1-26 are pending. Claims 18-26 were previously withdrawn. Claims 2-4, and 7-13 have been canceled. Claims 1, 5, 6, and 14-17 have been amended. Support for the amendments can be found in the claims and specification as originally filed and also, for example, in paragraphs [054], [059], [068], and [069]. Claims 27-32 are new. Support for the new claims can be found, for example, in paragraphs [0160] and [0161] on page 38.

With respect to all amendments and cancelled claims, Applicants have not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections and/or objections made by the Patent Office. Applicants reserve the right to pursue prosecution of any presently excluded claim embodiments in future continuation and/or divisional applications.

### **Rejection under 35 U.S.C. § 112, first paragraph**

#### ***1. Claims 1-3 and 5-9***

Claims 1-3 and 5-9 stand rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the enablement requirement. On pages 2-3 of the Office Action, the Examiner acknowledges the subject matter enabled by the specification. Without acquiescing to the Examiner's rejection and solely for the purpose of advancing prosecution, Applicants have amended claims 1, 5, and 6 to be consistent with the Examiner's acknowledgement of the enabled subject matter on pages 2 and 3 of the Office Action. Claims 2, 3, and 7-9 have been canceled. As such, Applicants respectfully submit that the rejection be withdrawn.

#### ***2. Claims 4 and 10-13***

Claims 4 and 10-13 stand rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the enablement requirement. Without acquiescing to the Examiner's rejection and solely for the purpose of advancing prosecution, Applicants have canceled claims 4 and 10-13. As such, Applicants respectfully submit that the rejection be withdrawn.

**Rejections under 35 U.S.C. §102(b)**

Claims 1-14 stand rejected as allegedly anticipated under 35 U.S.C. §102(b) by U.S. Patent Application No. 2002/0127205, Edge et al. (hereinafter “Edge”). For an anticipation rejection under 35 U.S.C. §102 to be proper, a single reference must expressly or inherently disclose each and every element of a claim. In re Paulsen, 31 USPQ2d 1671, 1673 (Fed. Cir. 1994); MPEP § 2131 (citing Richardson v. Suzuki Motor Co., 9 USPQ2d 1913, 1920 (Fed. Cir. 1989)). Applicant submits that Edge fails to disclose each and every element of the claims.

In particular, the method of amended claim 1 includes the step of “contacting *ex vivo* a target cell ... with an expression vector encoding all or a functional portion of a CD8  $\alpha$ -chain”; the method of amended claim 5 includes the step of “contacting *ex vivo* donor allograft cells ... with an expression vector encoding all or a functional portion of a CD8  $\alpha$ -chain”; and the method of amended claim 6 includes the step of “contacting *ex vivo* cells of said allograft with an expression vector encoding all or a functional portion of a CD8  $\alpha$ -chain”. As the Examiner acknowledges at page 4 of the action, Applicants have demonstrated that the CD8  $\alpha$  chain alone is required for inhibition of development of activated T cells.

In contrast, Edge’s disclosure regarding CD8 is directed to the  $\alpha$ : $\beta$  heterodimer form of CD8, including a prophetic description of cloning both chains in Example 5. Notably, no actual data is shown for CD8 expression and the teachings of this reference are largely speculative and non-enabling. In any event, there is no teaching or suggestion of Applicants’ invention as presently claimed. Since Edge fails to teach or suggest each limitation of the present claims, Applicants respectfully request that the 102(b) rejection be withdrawn.

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### CONCLUSION

Please direct any calls in connection with this application to the undersigned at (415) 781-1989.

Respectfully submitted,  
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